IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

LEONARD SOSNOWSKI,	)	
	)	
Plaintiff,	)	
	)	11 C 59
v.	)	
	)	Judge George W. Lindberg
WRIGHT MEDICAL TECHNOLOGY, INC.,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Before the court is defendant Wright Medical Technology, Inc.'s motion for summary judgment. For the reasons stated below, the motion is granted.

I. *Background*

The following facts are undisputed, unless otherwise noted. On April 13, 2006, x-rays taken of plaintiff's pelvis revealed end-stage degenerative joint disease in both hips. Plaintiff was diagnosed with bilateral degenerative osteoarthritis.

Plaintiff had left hip replacement surgery on May 2, 2006. The modular hip prosthesis used in this surgery was designed by defendant, and contained a Profemur® neck made of a titanium alloy. Before the surgery, plaintiff and his doctor signed an informed consent form, acknowledging that plaintiff had been advised and warned of the risks associated with his hip prosthesis, including the potential for failure. At the time of his surgery, plaintiff was five feet, six inches tall and weighed approximately 340 pounds.

Six weeks after his surgery, plaintiff reported that his left leg was strong and nearly pain-free. Plaintiff worked as a school custodian for a period of time between June 2007 and July 2008, a job in which his duties were physically demanding, and required him to do "an awful lot

of walking."

In October 2010, the modular neck in plaintiff's hip prosthesis fractured, due to fretting[1] and fatigue.[2] At that time, plaintiff weighed 438 pounds. The parties agree that plaintiff's weight directly contributed to the fracture. Plaintiff underwent revision surgery on October 9, 2010.

Plaintiff's amended complaint alleges claims of strict liability and negligence based on improper manufacture and design of the prosthesis, and failure to warn (Counts I and II); and breach of implied and express warranty (Counts III and IV). Defendant has moved for summary judgment as to all claims.

II. *Analysis*

Summary judgment shall be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court must draw all reasonable inferences in favor of the nonmoving party. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000). The moving party bears the initial burden of demonstrating that no material issue exists for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once the moving party has properly supported its motion, the nonmoving party must offer specific facts demonstrating that a material dispute exists, and must present more than a scintilla of evidence to

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[1] Plaintiff's expert defines "fretting" as "a special wear process that occurs at the contact area between two materials under load and subject to slight relative movement by vibration or some other force."

[2] According to plaintiff's expert, "fatigue" is a "mechanism by which a crack is both initiated and propagated through a structure when a varying applied load is applied into the structure."

support its position. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986).

A. *Manufacturing Defect and Breach of Warranty Claims*

Plaintiff concedes that that "the facts in this case do not support a claim for manufacturing defect" of the product at issue, and that his breach of implied and express warranty claims in Counts III and IV are time-barred. Accordingly, summary judgment is granted as to Counts I and II to the extent that they are based on a manufacturing defect theory, and as to Counts III and IV.

B. *Design Defect*

1. *Strict Liability*

In order to prevail on his strict product liability claim in Count I, plaintiff must show that his injury resulted from a condition of the product that was unreasonably dangerous. *See Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 335 (Ill. 2008). A product may be unreasonably dangerous based on a defect in the product's design. *See id.* A plaintiff may show that a product design was unreasonably dangerous using the "consumer-expectation test" or the "risk-utility test." *Id.* at 336. The Illinois Supreme Court has held that it is appropriate to combine the two tests where the evidence supports doing so, and where the parties have not both framed their theories of the case entirely in terms of consumer expectations. *See id.* at 352; *see also Show v. Ford Motor Co.*, 659 F.3d 584, 588 (7th Cir. 2011) (citing *Mikolajczyk v. Ford Motor Co.* and noting that "consumers' expectations are just factors 'included within the scope of the broader risk-utility test'"). Accordingly, the court will consider consumer expectations as a factor under the risk-utility test.

Under the risk-utility test, the plaintiff must present evidence "that the magnitude of the

danger outweighs the utility of the product, as designed." *Calles v. Scripto-Tokai Corp*., 864 N.E.2d 249, 257 (Ill. 2007). Under this test, the court first balances relevant factors to determine whether the case should be submitted to a jury. *Jablonski v. Ford Motor Co.*, 955 N.E.2d 1138, 1155 (Ill. 2011). If the plaintiff satisfies this threshold determination, the finder of fact then determines what weight to give any particular factor, with the relevance of the factors varying from case to case. *Id*.

In addition to consumer expectations, the court considers a "broad range of factors" under the risk-utility test, including:

- the product's utility to the user and to the public as a whole;
- the likelihood that the product will cause injury and the probable seriousness of the injury;
- the product's compliance with "design standards in the industry, design guidelines provided by an authoritative voluntary organization, or design criteria set by legislation or governmental regulation";
- the instructions and warnings accompanying the product; and
- the availability and feasibility of alternative designs at the time the product at issue was manufactured.

Mikolajczyk, 901 N.E.2d at 335, 352; *Calles*, 864 N.E.2d at 260. Although plaintiff need not present proof on each of these factors, he must offer enough evidence to show that a genuine issue of material fact exists as to whether the risks outweigh the benefits. *See Calles*, 864 N.E. 2d at 261.

The court begins by considering the utility factor. Plaintiff does not contend that defendant's hip prosthesis was not useful to the public as a whole. In addition, although plaintiff states that the prosthesis had little or no use to him, it is undisputed that plaintiff's left leg was

strong and nearly pain-free six weeks after his hip replacement, that plaintiff was able to work at a physically demanding job for at some time following his surgery, and that plaintiff had the hip prosthesis for more than four years before it fractured.

Next, the court considers the likelihood of injury factor. Fatigue tests defendant performed on the modular neck in 2000 showed that its fatigue endurance limit was estimated at 4,900 newtons, or approximately 1,100 pounds. Defendant acknowledged that in 2006, when plaintiff had his first surgery, defendant was aware that depending on the level of activity, a patient places loads of three to five times his body weight on a hip prosthesis.

Although plaintiff contends that defendant's file contained an October 24, 2006 memorandum reporting twelve cases of fractures of modular necks, defendant challenges the authenticity of plaintiff's evidence on this point. In support of his contention, plaintiff only cites a document titled "(TRANSLATION OF BATES WMT-SOS 000621)" and "WRIGHT" that states, in part:

> Subject: Review of complaints from clients concerning the fracture of the modular neck for the period 2002 to 2006.
>
> . . . .
>
> 2. As of the time of the client claims regarding the rupture of modular necks of 10/24/2006, there were 12 cases quoted below, with fractures in the oblong cone encasement and for which the femoral stem and femoral head were known.

Plaintiff does not offer an affidavit or testimony to authenticate or otherwise lay a foundation for this document, as required in summary judgment proceedings. *See Woods v. City of Chicago*, 234 F.3d 979, 988 (7th Cir. 2000) (stating that the court may consider "properly authenticated and admissible documents or exhibits" in summary judgment proceedings). Nor does plaintiff offer any evidence that this document was part of defendant's file. Accordingly, the court disregards it.

As of May 2, 2006, when plaintiff received his prosthesis, defendant states that it was aware of two fractures or failures of a Profemur® modular neck. It is undisputed that approximately twenty neck fractures occurred out of over 108,000 sales of defendant's hip prostheses through 2007, representing a failure rate of approximately .018%. In a December 1, 2008 safety alert sent to health care professionals, defendant stated that it had received reports of 35 modular neck failures as of November 21, 2008, out of more than 130,000 units sold, and that an initial investigation revealed the following commonalities in the failures: heavy-weight males, long modular necks, and patient activities such as heavy lifting and impact sports. It is undisputed that as of December 2010, after ten years on the market, the highest neck fracture rate reported for the hip prosthesis configuration at issue in this case was 0.36%, a similar or lower fracture rate than most reported in the medical literature.

As for the industry standards factor, defendant has offered evidence that the standard used in the United States and European markets at the time relevant to this action was the "ISO" standard. In 2000, defendant received clearance from the Food and Drug Administration ("FDA") to sell the hip prosthesis at issue here through the "510(k) process." Under that process, defendant received clearance based on the FDA's determination that defendant's prosthesis was "substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments." As part of that process, defendant submitted to the FDA a report that defendant had performed a fatigue test on the prosthesis to assess its performance under a maximum force of 2300 newtons (517.1 pounds), and that the test concluded that the prosthesis "should provide a safe clinical outcome in total hip replacement for the scenarios addressed by this test."

Defendant's expert, Jorge Ochoa, opined that the "[s]tatic and fatigue testing conducted as described in [defendant's] 510(k) submission was adequate and consistent with normal industry practices."

Plaintiff notes that medical literature available in 1996 contained test data indicating that hip prostheses are subjected to three to five times the patient's body weight. Plaintiff contends that based on this data, the standard defendant used was inadequate. Plaintiff also takes issue with the FDA's 510(k) process, which he argues does not involve rigorous review. However, plaintiff does not dispute that defendant received clearance from the FDA to sell the prosthesis, or that defendant's design complied with the ISO standard. Nor does plaintiff offer evidence that the medical literature he cites represented an industry standard, an authoritative voluntary organization's design guidelines, or design criteria set by legislation or governmental regulation. The court finds that the compliance with industry standards factor does not weigh in favor of plaintiff.

The court next considers the instructions and warnings accompanying the product. As discussed more fully below relating to plaintiff's failure to warn claim, the Instructions for Use for defendant's hip prosthesis stated: "An overweight or obese patient can produce high loads on the prosthesis which can lead to failure of the prosthesis." Although plaintiff contends that this warning should have provided more detailed information, such as a specific weight limit, the court finds that this factor weighs in favor of defendant.

Regarding the alternative design factor, plaintiff argues that defendant could have used a cobalt chromium modular neck instead of the titanium neck. In support of this argument, plaintiff cites evidence that defendant now recommends that patients over 230 pounds use a hip

prosthesis with a cobalt chromium modular neck because that alloy is stronger and more resistant to heavy loads. In his statement of additional material facts, plaintiff also cites the testimony of Brian McDaniel, an engineer employed by defendant, who acknowledged that defendant's modular necks could have been manufactured from cobalt chromium in 2000 or 2001 without materially affecting the cost of the product. Plaintiff's expert, Mitchell Kaplan, concluded that defendant's use of titanium "was inappropriate as it is susceptible to fretting fatigue," and opined that the use of an alternative material such as cobalt chromium "appears to be a valid substitution."

Defendant's expert, engineer Jorge Ochoa, stated that the titanium alloy used in the modular necks at issue in this case "has a long history of clinical success in orthopaedic surgery due to its superior biocompatibility, fatigue properties, and strength," and that because of the physical properties of titanium, titanium components "are able to interface with the largest variety of femoral head materials possible." Although Ochoa acknowledged that designing a modular neck with chromium alloys may increase the strength of the neck components, he stated that "a simultaneous reduction in disassembly strength may be a resulting performance by-product."

Defendant's other expert, Brad James, stated that titanium "is a widely accepted engineering alloy, with extensive use for biomedical implants, including many current modular hip systems." James noted that titanium alloys have superior stiffness characteristics and biocompatibility than other implantable alloys, such as cobalt chromium. James stated that cobalt chromium alloys have increased stiffness, which can lead to bone resorption and implant loosening. In addition, James stated that cobalt ions "may be allergenic/carcinogenic, and thus

any corrosion, leaching, or wear could have deleterious effects compared to titanium."

Although plaintiff's expert offered the conclusion that cobalt chromium "appears to be a valid substitution" for titanium, he does not address the evidence that cobalt chromium alloys have increased stiffness, which can lead to bone resorption and implant loosening, or that use of cobalt chromium may result in a reduction in disassembly strength as a performance by-product. Nor did plaintiff's expert compare the biocompatibility of titanium alloys and cobalt chromium alloys in hip prostheses. Moreover, as defendant notes, plaintiff's expert stated in his report that based on applicable literature, "fretting corrosion occurs regardless of the materials in contact, i.e. whether they be dissimilar [titanium/cobalt chromium] or similar both being [cobalt chromium]."

The court concludes that plaintiff has not shown that a prosthesis made from cobalt chromium is a better alternative to titanium. "It is not sufficient that the alternative design would have reduced or prevented the harm suffered by the plaintiff if it would also introduce into the product other dangers of equal or greater magnitude." *Jablonski*, 955 N.E.2d at 1158 (quoting Restatement (Third) of Torts: Products Liability § 2, cmt. f, at 23 (1998)). While the experts agree that cobalt chromium is stronger than titanium, plaintiff has not addressed defendant's evidence that titanium has other benefits and cobalt chromium has other risks, and has offered no information as to the failure rate in cobalt chromium prostheses. The court also notes that evidence that defendant now recommends that patients over 230 pounds use a hip prosthesis with a cobalt chromium neck, is not admissible to show that the titanium design was defective. *See* Fed. R. Evid. 407 (evidence of a subsequent remedial measure is not admissible to prove a defect

in a product or its design).[3]

Finally, the court considers the consumer expectation factor. Under the consumer-expectation test, the plaintiff must present "evidence that the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner." *Mikolajczyk*, 901 N.E.2d at 336 (quoting *Lamkin v. Towner*, 563 N.E.2d 449, 457 (Ill. 1990)). The Seventh Circuit has suggested that in cases involving complex devices, expert testimony may be necessary under the consumer expectation test. *See Show*, 659 F.3d at 585-87. The court concludes that defendant's hip prosthesis is a complex device, and that plaintiff was required to present expert evidence as to consumer expectations. Plaintiff has failed to offer such evidence, and therefore this factor does not favor plaintiff.

It is undisputed that as of 2006, defendant was aware that a patient applies force of three to five times his body weight to a hip prosthesis, and that the maximum fatigue strength of defendant's modular necks was 1,100 pounds. While the risk of plaintiff's type of injury was foreseeable, however, plaintiff has not offered evidence showing that these risks outweighed the benefits. *See Jablonski*, 955 N.E.2d at 1157 (explaining that the plaintiff was required to present evidence "that the risk was foreseeable and that the risks inherent in the product design outweighed the benefits"). Defendant has offered evidence that it complied with industry standards, and that its device's highest fracture rate was similar to, or lower than, most reported in the medical literature. Plaintiff has not offered evidence that its proposed alternative, a cobalt

[3] Subsequent remedial measures may be admissible for the purpose of showing the feasibility of precautionary measures in cases in which feasibility is disputed. *See* Fed. R. Evid. 407. Here, however, defendant has acknowledged that it could have made the device from cobalt chromium for the same cost, and has not disputed feasibility.

chromium device, would be stronger without introducing other risks. Finally, defendant's instructions for use warned that obese patients could produce high loads on the prosthesis which could lead to its failure, the precise risk about which plaintiff complains. Because plaintiff has not offered evidence that the risks of defendant's prosthesis outweighed its benefits, the court concludes that no reasonable jury could find in plaintiff's favor on his strict products liability claim based on a design defect theory.

The court notes that the district court in the Central District of Illinois recently granted summary judgment in the defendants' favor in a similar case. In *Cappellano v. Wright Med. Group*, the plaintiff, a 276-pound man, received a modular hip prosthesis with a neck made of titanium alloy. *See* No. 08-CV-2265, 2012 WL 187119, at * 1 (C.D. Ill. Jan. 23, 2012). The neck of the prosthesis fractured approximately three-and-one-half years after it was implanted. *See id*. at * 1-2. The plaintiff brought a claim of strict product liability against manufacturer Wright Medical Technology (the defendant here) and other related entities, based on manufacturing and design defect theories. *See id.* at *7-9.

In summary judgment proceedings, the plaintiff in *Cappellano* argued that defendant could have used an alternate monolithic (as opposed to modular) design, or a cobalt chromium neck. *See id.* at *11. The court concluded that because the plaintiff had not addressed the defendant's evidence of the other advantages of a titanium device, plaintiff provided no basis for the court to determine whether the risks associated with the titanium device outweighed its benefits. *See id.* at 12-13. The court also concluded that the plaintiff had not provided adequate expert testimony on the issue of consumer expectations. *Id*. at *13. The court accordingly found that plaintiff had not adequately shown that the risks of the design outweighed the benefits, and

granted summary judgment as to plaintiff's design defect claim. *Id*. at *14-15. This court finds the *Cappellano* court's reasoning persuasive.

2. *Negligent Design*

To prevail on his negligent design claim in Count II, plaintiff must show that, "in the exercise of ordinary care," defendant "should have foreseen that the design would be hazardous to someone." *See Jablonski*, 955 N.E.2d at 1154. The test for determining whether a defendant's conduct in designing a product was unreasonable is "essentially identical" to the balancing test used in strict liability cases. *See id.* at 1155. For the same reasons discussed above relating to plaintiff's strict liability claim in Count I, summary judgment is granted as to plaintiff's negligent design claim in Count II.

C. *Failure to Warn*

A product may also be unreasonably dangerous, and thus subject to strict liability, based on a manufacturer's failure to warn of the danger or instruct on the proper use of the product. *See Mikolajczyk*, 901 N.E.2d at 335. Plaintiff claims that defendant failed to provide adequate warnings to plaintiff and his physicians because defendant's warnings did not specify the maximum weight the prosthesis could bear. Defendant argues that it is entitled to summary judgment under this theory because it provided plaintiff's doctor with adequate warnings.

Illinois courts apply the "learned intermediary" doctrine, which provides that the manufacturer of a prescription medical device generally has a duty to warn prescribing health professionals of the device's known dangerous propensities, rather than the patient. *Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 42 (Ill. 2002). The adequacy of the warning "must be judged by whether it sufficiently apprises physicians of the risks associated with the use" of the

medical device. *See Hernandez v. Schering Corp.*, 958 N.E.2d 447, 455 (Ill. App. Ct. 2011). Since "[o]nly a physician or someone with specialized knowledge would be qualified to determine whether the warning was inadequate," expert testimony is required. *See id.* at 455-56; *N. Trust Co. v. Upjohn Co.*, 572 N.E.2d 1030, 1036 (Ill. App. Ct. 1991).

Defendant has offered undisputed evidence that it provided Instructions for Use of the hip prosthesis that included the following information:

- Patient's weight. An overweight or obese patient can produce high loads on the prosthesis which can lead to failure of the prosthesis.
- Patient's occupation or activity. If the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not resort to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
- The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the prosthesis does not replace normal healthy bone, that the prosthesis can break or become damaged as a result of certain activity or trauma, has a finite expected service life, and may need to be replaced at some time in the future.

Plaintiff contends that this warning was inadequate because defendant did not provide a specific weight limitation for the prosthesis. However, plaintiff offers no expert evidence that defendant's warning failed to sufficiently apprise physicians of the risks associated with the use of the prosthesis. Moreover, defendant warned of the precise risk that plaintiff now complains of in this case, and that warning was not inaccurate or misleading. The court concludes that plaintiff has not created a genuine issue of fact as to his failure to warn claim. Defendant's motion for summary judgment is granted as to this claim.

ORDERED: Defendant's motion for summary judgment [80] is granted. Judgment in

favor of defendant Wright Medical Technology, Inc. and against plaintiff Leonard Sosnowski will be set forth on a separate document and entered in the civil docket. *See* Fed. R. Civ. P. 58(a); 79.

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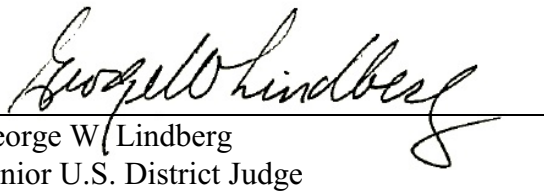

George W. Lindberg
Senior U.S. District Judge

DATED: March 27, 2012